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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**APPLICANT:** Todd M. Boyce et al. **EXAMINER:** B. Pellegrino  
**SERIAL NO.:** 09/745,643 **GROUP ART UNIT:** 3738  
**FILED:** December 22, 2000 **DATED:** April 23, 2004  
**FOR:** KEYED INTERVERTEBRAL DOWEL **DOCKET:** 285-113 CON

Mail Stop: AF  
Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF APPELLANTS' BRIEF ON APPEAL**

Sir:

Enclosed please find APPELLANT'S BRIEF in triplicate.

Also enclosed is a check in the amount of \$165.00 (small entity) to cover the appeal fee.

If the enclosed check is insufficient for any reason or becomes detached, please charge the required fee under 37 C.F.R. §1.17 to Deposit Account No. 04-1121. Also, in the event any additional extensions of time are required, please treat this paper as a petition to extend the time as required and charge Deposit Account No. 04-1121. TWO COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

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Dated: April 23, 2004

  
Maria Goldman



Attorney Docket: 285-113 CON

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**APPELLANTS' BRIEF**

Sir:

**(1) REAL PARTY IN INTEREST**

The real party in interest is Osteotech, Inc., the assignee of the subject application, having an office at 51 James Way, Eatontown, NJ 07724.

**(2) RELATED APPEALS AND INTERFERENCES**

To the best of appellants' knowledge and belief, there are no related appeals or interferences.

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this Appellants' Brief in triplicate is being deposited with the United States Postal Service as first class mail, postpaid in an envelope addressed to the: Mail Stop: AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 23, 2004.

Dated: April 23, 2004

  
Maria Goldman

### **(3) STATUS OF CLAIMS**

Of original Claims 1-27, Claims 10-17 and 25-27 were withdrawn from consideration (Office Action mailed April 19, 2002), Claims 1, 2, 20, 21 and 22 were amended and Claims 3, 18 and 19 were cancelled in the Amendment filed July 22, 2002 and Claim 1 was again amended in the Amendment filed on December 13, 2002 accompanying appellants' RCE.

All of the pending claims, i.e., Claims 1, 2, 4-17 and 21-24, stand finally rejected and constitute the claims on appeal. A copy of the appealed claims is contained in the Appendix.

### **(4) STATUS OF AMENDMENTS**

There has been no amendment filed subsequent to the final rejection set forth in the Office Action of August 27, 2003.

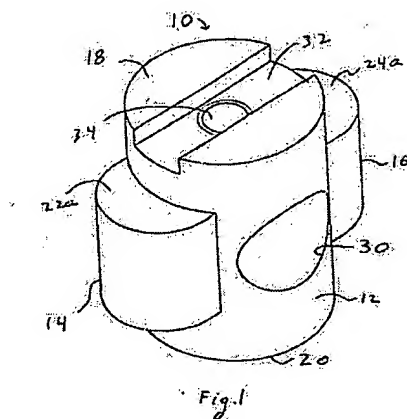
### **(5) SUMMARY OF THE INVENTION**

The appealed claims are directed to an implant, more specifically, an intervertebral implant, for installation in the space between adjacent vertebra ("intervertebral space") previously occupied by an intervertebral disc that has degenerated through trauma or pathology (Claims 1, 2, 4-9, 20-22 and 24) and to a method for installing an intervertebral implant within an intervertebral space (Claim 23).

The intervertebral implant of the invention is employed in a procedure resulting in the fusion of adjacent vertebrae. The claimed intervertebral implant may be formed in

whole or in part from bone or material derived from bone so that it biologically performs like bone to encourage new bony ingrowth and accelerate fusion of adjacent vertebrae. The unique configuration of the claimed intervertebral implant prevents or inhibits its post-installation movement or expulsion.

The structure of the claimed intervertebral implant can be readily understood and appreciated from a consideration of the embodiment of the implant shown in Fig. 1 of the specification which is reproduced below:



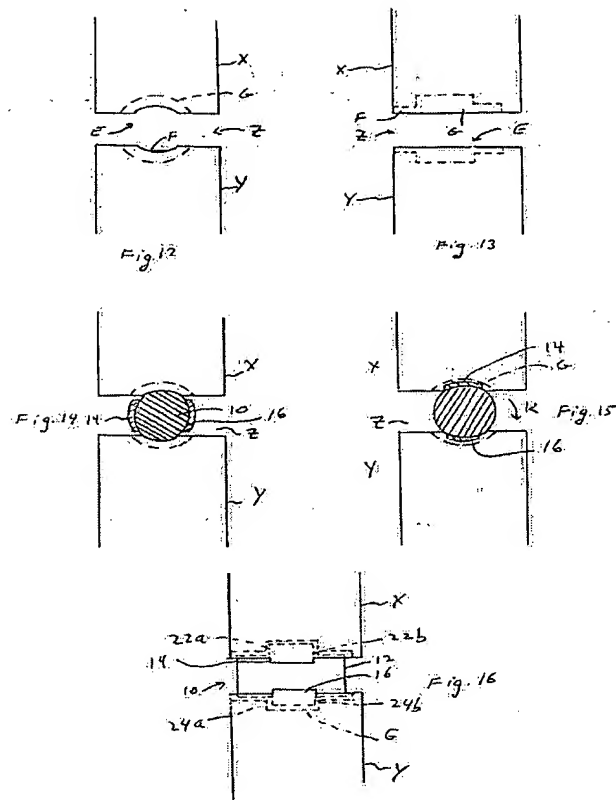
As described in the specification at page 12, line 18 to page 14, line 2, intervertebral implant 10 of Fig. 1 includes a substantially cylindrical body portion 12 having a pair of diametrically opposed and radially extending tabs 14 and 16, a first end 18 and a second end 20. Tab 14 has first and second engaging or retaining surfaces 22a and 22b which are stepped or longitudinally spaced a predetermined distance from first end 18 and second end 20, respectively. Similarly, tab 16 has a pair of retaining surfaces 24a and 24b which are stepped or longitudinally spaced from a first end 18 and second end 20, respectively.

Retaining surfaces 22a, 22b and 24a, 24b are configured to engage a portion of adjacent vertebrae when installed therebetween.

As shown in Fig. 1, tabs 14 and 16 extend along a limited portion of the circumference of substantially cylindrical body portion 12. Preferably, tabs 14 and 16 are radially spaced 180° apart. Tab 14 includes a rounded side surface 26 and tab 16 includes a rounded side surface 28. These rounded surfaces facilitate the installation of intervertebral implant 10 within the intervertebral space, a procedure which will be briefly described below.

Intervertebral implant 10 includes a throughbore 30 which has a longitudinal axis substantially perpendicular to the longitudinal axis of the implant. Intervertebral implant 10 further includes an installation slot 32 machined or milled in first end 18. A second bore 34 extending between slot 32 and throughbore 30 is provided for mating of the implant with an insertion tool. Throughbore 30 is dimensioned to receive one or more materials that encourages new bone growth such as bone particles and/or other biocompatible osteoinductive or osteoconductive material including cancellous bone, cancellous bone particles, ceramics, polymers, composites, bone morphogenetic protein (BMP), etc.

Installation of the intervertebral implant of Fig. 1 in an intervertebral space prepared for its reception is schematically illustrated in Figs. 12 to 16 of the specification and reproduced below:



As described at page 16, line 3 to page 17, line 10 of appellants' specification, the procedure for installing intervertebral implant 10 of Fig. 1 is described in Figs. 12-16 in connection with adjacent vertebrae X and Y defining intervertebral space Z therebetween. The endplate, i.e., the end surface, of a vertebra, or vertebral body, is made up of stronger bone than that of its cancellous interior. Thus, recesses formed within the endplates of vertebral bodies X and Y will permit tabs 14 and 16 of intervertebral implant 10 to extend past the endplates of adjacent vertebrae and into the surrounding softer cancellous bone. Rotating intervertebral implant 10 into place will cause the cancellous bone to be

compressed against the body of the implant thereby providing additional frictional resistance against implant movement. A drill or other known devices and methods are utilized to form a stepped hole, or bore E, between the adjacent vertebrae, preferably by milling or machining. Stepped hole E preferably has a narrow diameter portion F adjacent the outer surface of the vertebrae and an enlarged portion G, or recess, interior to the vertebrae. As shown in Fig. 14, intervertebral implant 10 is inserted between vertebrae X and Y such that tabs 14 and 16 are initially aligned with intervertebral space Z. Intervertebral implant 10 is inserted into the drilled hole a sufficient distance such that tabs 14 and 16 align with recess G of bore E. Intervertebral implant 10 is subsequently rotated approximately 90° (Figs. 15 and 16) such that tabs 14 and 16 enter recess G. Once rotated into this position, retaining surfaces 22a and 22b on tab 14 and retaining surfaces 24a and 24b on tab 16 engage edges of recess G of bore E preventing or inhibiting expulsion of the implant.

#### **(6) ISSUES**

The issues presented by this appeal for consideration and determination by the Board are:

I. Does Marino U.S. Patent No. 6,290,724 ("Marino") anticipate the intervertebral implant of Claims 1, 2, 4, 5, 8, 9, 21 and 24?

II. Does Godefroy et al. U.S. Patent No. 5,683,463 ("Godefroy et al.") in view of Bianchi et al. U.S. Patent No. 6,033,438 ("Bianchi et al.") evidence the obviousness of the intervertebral implant of Claims 1, 2, 4-7 and 9?

III. Does Marino in view of Scarborough U.S. Patent No. 5,676,146 ("Scarborough") evidence the obviousness of the intervertebral implant of Claim 20?

IV. Does Marino in view of Lewandrowski et al., J. Biomat. Res. (1966)

("Lewandrowski et al.") evidence the obviousness of the intervertebral implant of Claim 22?

V. Does Marino in view of Kuslich et al. U.S. Patent No. 5,445,639 ("Kuslich et

al.") evidence the obviousness of the method of installing an intervertebral implant of Claim 23?

### **(7) GROUPING OF CLAIMS**

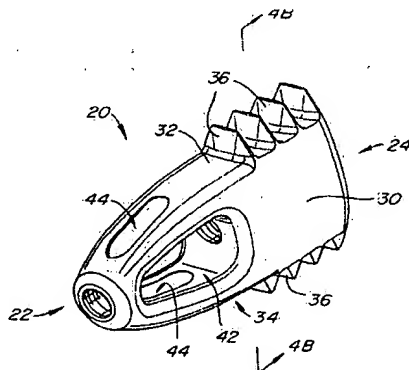
For the grounds of rejection applying to Claims 1, 2, 4, 5, 8, 9 and 21 (Issue I, *supra*) and to Claims 1, 2, 4-7 and 9 (Issue II, *supra*), these claims may be regarded as standing or falling together.

### **(8) ARGUMENT**

#### **I. MARINO FAILS TO ANTICIPATE THE INTERVERTEBRAL IMPLANT OF CLAIMS 1, 2, 4, 5, 8, 9, 21 AND 24**

##### **A. The Rejection of Claims 1, 2, 4, 5, 8, 9, 21 and 24 for Anticipation By Marino**

Marino discloses an intervertebral insert, or implant, which is illustrated in Fig. 1A of the patent and is reproduced below.





The Examiner applies Marino as an anticipation of the intervertebral implant of Claims 1, 2, 5, 8, 9, 21 and 24 as follows (final Office Action mailed August 27, 2003):

...Marino shows (Fig. 1A) a "substantially" cylindrical body with at least two tabs 36 longitudinally placed from the two ends of the vertebral implant. The use of "substantially cylindrical body" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be seen that the tabs are radially spaced that a first tab is approximately 180° from a second tab on the opposite side. It can also be seen that there is a throughbore 42 which is perpendicular to the longitudinal axis and radially spaced from the tabs. The tabs have a width less than or *equal* to the maximum diameter of the body. Marino discloses the implant is formed from bone or material derived from bone, col. 6, lines 31-42. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses."

B. Marino Fails to Disclose Several Limitations of the Intervertebral Implant of Claims 1, 2, 5, 8, 9, 21 and 24

In order to constitute an anticipation of a claim under 35 U.S.C. §102, a single prior art reference must disclose each and every limitation of the claim, either expressly or inherently. *See, e.g., EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 USPQ2d 1423 (Fed. Cir. 2001) ("A prior art reference anticipates a claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

Marino fails to disclose the following limitations of the intervertebral implant of Claim 1:

1. A "substantially cylindrical body portion";
2. "at least two tabs extending radially outward from the substantially cylindrical body portion"; and,

3. "at least two tabs...possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body".

In failing to disclose any of these limitations in the appealed claims much less all three, Marino et al. fails to anticipate appellants' claimed intervertebral implant.

1. There is no Disclosure in Marino of a "substantially cylindrical body portion".

Claim 1 recites the limitation "a substantially cylindrical body portion". Nowhere in Marino is there a disclosure of any implant possessing a "substantially cylindrical body portion". On the contrary, the various views of the Marino implant illustrated in the drawings are that of an implant whose body is clearly noncylindrical.

The Examiner asserts that the expression "substantially cylindrical" is terminology of relative degree and is to be regarded as relatively unlimited. Such is not the case. The Federal Circuit Court of Appeals has summarized the relevant law in *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). In reversing the trial court's holding of invalidity on the ground that the claim expressions "approach each other", "close to", "substantially" and "closely approximate" were too vague to satisfy the requirement for definiteness of 35 U.S.C. §112, the Court said (847 F.2d at 821-22, 6 USPQ2d at 2012):

...The criticized words are ubiquitous in patent claims. Such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts...

See also MPEP 2173.05(b) (Relative Terminology), Subsection D ("Substantially") indicating that the term "substantially" may be considered a sufficiently definite limitation when viewed within the context of the specification. In appellants' specification, all of the

embodiments of the claimed intervertebral implant possess a "substantially cylindrical body", the term "substantially" being readily understood by one skilled in the art as designating a geometry which permits some slight deviation from that which is perfectly cylindrical. As such, the claim recitation "substantially cylindrical body" is a meaningful limitation, one that distinguishes the claimed intervertebral implant from the Marino noncylindrical implant.

2. There is no disclosure in Marino of "at least two tabs extending radially outward from the substantially cylindrical body portion".

The anchoring fins of the Marino implant extend outwardly from the body of insert 20 but they cannot be said to extend *radially* outward as in appellants' claimed intervertebral implant. As clearly illustrated in all of the embodiments of the Marino implant shown in the drawings, the anchoring fins are attached to that portion of insert 20 which does not possess a substantially cylindrical body portion. Lacking a substantially cylindrical body portion, the Marino implant lacks a radius and lacking a radius, the Marino anchoring fins cannot be said to extend radially outward.

3. There is no disclosure in Marino of "at least two tabs... possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body".

Marino's implant possesses a series of knife-like anchoring fins 36 which, in contrast to the "at least two tabs" of appellants' claimed intervertebral implant, are *not* configured and/or dimensioned to complement the configuration and dimensions of recesses *preformed* within a vertebral body. The purpose of Marino's fins is to cut or slice into the vertebral endplates and occupy the thus-formed grooves or slits; the grooves or slits are *not preformed* only to be later occupied by the fins, they are formed *at the same instant* as they are occupied by the fins.

The Examiner asserts that appellants' claims recite an "intended use" which can be given no weight in the absence of any distinguishing structure. While it is correct to say that the recitation of a use, or utility, carries no patentable weight in and of itself, appellants' claims do not recite an intended use. Applicants' claims do recite that each of the at least two tabs extending radially outward from the substantially cylindrical body possess a "configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body". This recitation is *not* a recitation of intended use but clearly one of structure, specifically, the structure of the tabs. The structure of the tabs is such that they are adapted to be received within suitably configured *preformed recesses* formed in the vertebral endplates as distinguished from the Marino et al. knife-like anchoring fins which are designed to *cut or slice into* the vertebral endplates and simultaneously occupy the thus-formed grooves or slits.

The Examiner's characterization of Marino's knife-like anchoring fins 36 as "tabs" would seem to be an attempt to shoehorn the Marino disclosure of "fins" into appellants' claim recitation of "tabs". While it is recognized that the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997) ("[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art...."); *In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) ("It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification,...and that claim language should be read in light of the specification *as it would be interpreted by one of ordinary skill in the art.*") (emphasis added).

Appellants' specification uses the term "tab" to designate a structure that can be fitted into a preformed recess situated within a vertebral body but by virtue of its configuration and dimensions that allow it to accomplish this, is *incapable* of forming its own recess. However, Marino's knife-like anchoring fins 36 are specifically configured and dimensioned to create the grooves or slits which they simultaneously occupy. The two structures, appellant's tabs and Marino's ribs, are in fact, mutually incompatible structures. The Examiner's interpretation of the claim term "tabs" to read on Marino's knife-like fins is entirely inconsistent with appellants' specification as it would be understood by one skilled in the art.

II. THE COMBINED DISCLOSURES OF GODEFROY ET AL. AND BIANCHI ET AL. TAKEN AS A WHOLE FAIL TO EVIDENCE THE OBVIOUSNESS OF THE INTERVERTEBRAL IMPLANT OF CLAIMS 1, 2, 4-7 AND 9.

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A. The Rejection of Claims 1, 2, 4-7 and 9 for Obviousness  
Over Godefroy et al. in View of Bianchi et al.

Godefroy et al. discloses an intervertebral implant illustrated in Fig. 6 which is reproduced below:

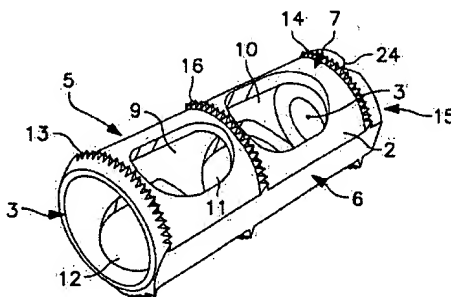


FIG. 6

The Examiner has combined Godefroy et al. with Bianchi et al. which discloses intervertebral implants made from bone. The Examiner's application of Godefroy et al. and

Bianchi et al. to the rejected claims is as follows (final Office Action mailed August 27, 2003):

...Fig. 6 [of Godefroy et al.] shows a "substantially" cylindrical body having at least two tabs 16, 14 radially spaced approximately 180° about the body of the implant and have a width at least less than or *equal* to the maximum diameter of the body. It can also be seen there is at least one throughbore 9. Fig. 1 shows a body portion with one end having an installation slot 24 and a bore 23 between the slot. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses." However, Godefroy et al. do not disclose the use of bone for the implant. Bianchi et al. teach the advantages of using bone as an implant, i.e., it allows excellent postoperative imaging, col. 2, lines 13-26. Bianchi also teaches that intervertebral implants are made from the bone, col. 5, lines 40-58. Bianchi additionally teaches that bone implants with surface features aid in stabilization and facilitate fusion, col. 8, lines 11, 12. It would have been obvious to one of ordinary skill in the art to use bone as taught by Bianchi et al. for the implant of Godefroy et al. in order to provide a preserved biological material that is fully capable of being stabilized in the vertebrae while also facilitating fusion.

B. The Combination of Godefroy et al. and Bianchi et al. Taken as a Whole Fails to Disclose or Suggest the "At Least Two Tabs... Possessing a Configuration and Dimensions Complementing the Configuration and Dimensions of Corresponding Preformed Recesses within a Vertebral Body" Limitation of the Intervertebral Implant of Claims 1, 2, 4-7 and 9

As in the rejection based on Marino, discussed *supra*, the Examiner construes the claim term "tabs" to read on an altogether different structure in the Godefroy et al. implant, specifically, toothed ribs 13, 14 and 16 of the implant. In their configuration, dimensions and function, the Godefroy et al. toothed ribs are similar to the knife-like anchoring fins of the Marino implant discussed *supra*. Thus, the toothed ribs of the Godefroy et al. implant simultaneously form, and occupy, indentations in the vertebrae thereby preventing axial displacement and rotation of the implant (specification, column 2, lines 57-60). Even were the Godefroy et al. implant made from bone (which the Examiner considers to be suggested by Bianchi et al.), it would nevertheless lack the critical and patentably distinguishing

feature of the claimed intervertebral implant's "at least two tabs...possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body".

As in the case of the anticipation rejection based on Marino, *supra*, the Examiner asserts that the aforequoted limitation is one of intended use and as such can carry no weight in the absence of distinguishing structure. Again, appellants point out that the limitation in question is not one of use but goes to the *structure* of the tabs. Consider this: the "at least two tabs" feature of the claimed intervertebral implant cannot be dimensioned and configured to complement the dimensions and configuration of *preformed* recesses and at one and the same time be dimensioned and configured to act as cutting or chiseling elements that form their own recesses. Giving the claim term "tab" its broadest reasonable construction does not countenance giving the term a construction that is *inconsistent* with what is described in the specification.

In conclusion, then, a Godefroy et al. implant, even one made from bone, does not suggest the "at least two tabs...performed recesses within a vertebral body" feature of the claimed intervertebral implant.

### III. THE COMBINED DISCLOSURES OF MARINO AND SCARBOROUGH TAKEN AS A WHOLE FAIL TO EVIDENCE THE OBVIOUSNESS OF THE INTERVERTEBRAL IMPLANT OF CLAIM 20

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#### A. The Rejection of Claim 20 for Obviousness Over Marino in View of Scarborough

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The Examiner has applied Marino and Scarborough to Claim 20 as follows (final Office Action mailed August 27, 2003):

...Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

B. The Combination of Marino and Scarborough Taken as a Whole Fails to Disclose or Suggest the "At Least Two Tabs...Possessing a Configuration and Dimensions Complementing the Configuration and Dimensions of Corresponding Preformed Recesses Within a Vertebral Body" Limitation of the Intervertebral Implant of Claim 20

Appellants' have explained above in connection with the rejection for anticipation by Marino that by reason of the structure of the "at least two tabs...feature of the claimed invention, specifically the configuration and dimensions of the tabs, the tabs are able to fitted within complementary configured and dimensioned recesses *preformed* in adjacent vertebral bodies whereas knife-like anchoring fins 36 of the Marino implant are designed to cut or slice into the vertebral bodies and simultaneously occupy the thus-formed grooves or slits. One skilled in the art would understand from appellants' specification that the claimed "at least two tabs..." feature due to its configuration and dimensions functions in a different manner from Marino's fins and *vice versa*. It can only be concluded that the Marino and Scarborough patents taken as a whole do not disclose or suggest this critical limitation of the claimed intervertebral implant.



IV. THE COMBINED DISCLOSURES OF MARINO AND LEWANDROWSKI ET AL. TAKEN AS A WHOLE FAIL TO EVIDENCE THE INTERVERTEBRAL IMPLANT OF CLAIM 22

A. The Rejection of Claim 22 for Obviousness Over Marino in View of Lewandrowski et al.

The Examiner has applied Marino and Lewandrowski et al. to Claim 22 as follows

(final Office Action mailed August 27, 2003):

...Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

B. The Combination of Marino and Lewandrowski Taken as a Whole Fails to Disclose or Suggest the "At Least Two Tabs...Possessing a Configuration and Dimensions Complementing the Configuration and Dimensions of Corresponding Preformed Recesses Within a Vertebral Body" Limitation of the Intervertebral Implant of Claim 22

As explained above, knife-like anchoring fins 36 of the Marino implant are not configured and dimensioned to occupy *preformed* recesses within adjacent vertebral bodies but, rather, to dig into the endplates of adjacent vertebral bodies where they will simultaneously occupy the thus-formed grooves or slits. Structurally, Marino anchoring fins 36 are configured and dimensioned to function quite differently from the "at least two tabs" feature of the intervertebral implant of Claim 22 which possess "a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body". Given these differences in structure, the combination of Marino and Lewandrowski et al. cannot be said to suggest the intervertebral implant of Claim 22.

V. MARINO AND KUSLICH ET AL. CANNOT PROPERLY BE COMBINED  
TO EVIDENCE THE OBVIOUSNESS OF THE IMPLANT INSTALLATION  
METHOD OF CLAIM 23

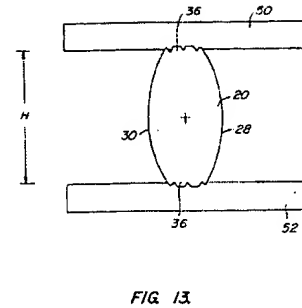
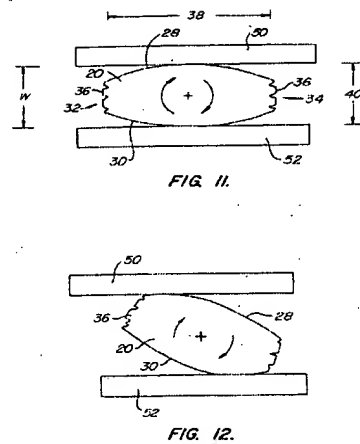
A. The Rejection of Claim 23 for Obviousness Over Marino  
in View of Kuslich et al.

The Examiner has applied Marino and Kuslich et al. to Claim 23 as follows (final  
Office Action mailed August 27, 2003):

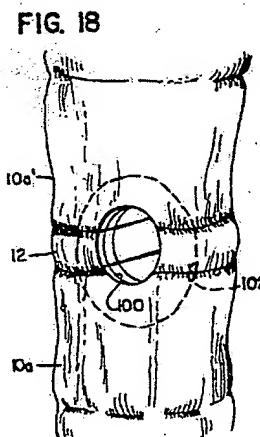
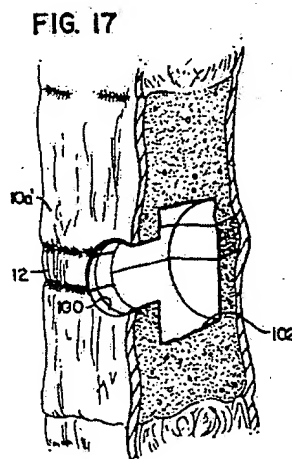
...Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7, lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore or cavity formed for the implant is designed such that the implant is secured in place, col. 4, lines 56,57. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion such that the cavity formed accommodates the structure of the implant as taught by Kuslich et al. for inserting the implant of Marino with tabs in the implanting procedure. As a result, the enlarged area for the implant with tabs is ready to receive the device and not require any forceful rotation or positioning causing trauma to the patient.

B. The Examiner Has Failed to Adequately Support the Selection  
and Combination of Marino and Kuslich et al. to Render  
Obvious the Implant Installation Method of Claim 23

Marino, as pointed out above, describes an intervertebral implant that is installed by inserting the implant within the intervertebral space and rotating the implant so that its knife-like anchoring fins 36 dig into the endplates of the adjacent vertebral bodies thereby becoming simultaneously lodged within the grooves or slits formed therein. The Marino implant installation method (described in column 13, lines 22-66) is schematically illustrated in Figs. 11, 12 and 13 which are reproduced below:



Kuslich et al. describes a method for achieving spinal fusion (specification, column 7, line 30 to column 8, line 15) which involves drilling a bore 100 through an intervertebral disc with part of the bore extending into the endplates of the adjacent vertebrae and thereafter reaming out a portion of the bore to provide a chamber 102 which is then filled with a graft medium such as finely chopped cortical or cancellous bone chips. The end result of these drilling and reaming operations is illustrated in Figs. 17 and 18 of Kuslich et al. which are reproduced below.



The specific rationale given for the rejection of the implant installation method of Claim 23 is based upon an incomplete and/or erroneous understanding of the Kuslich et al. spinal fusion method.

In the Kuslich et al. spinal fusion method, the drilling step results in the removal of only a portion of diseased disc tissue 12. The resulting bore 100 is incapable of receiving an implant such as that recited in Claim 23 which possesses tabs that radially extend beyond a substantially cylindrical body. If the diameter of the substantially cylindrical body were about the same diameter of bore 102, its tabs would prevent it from being inserted in the intervertebral space. If the diameter of the substantially cylindrical body were made small enough so that it and its radially extending tabs could be inserted through bore 100, the tabs could not possibly make engagement with chamber 102 thus frustrating the purpose of the tabs feature, namely, to engage recesses thereby preventing or inhibiting expulsion of the implant.

In point of fact, the Kuslich et al. spinal fusion method cannot be practiced with an implant having any kind of projecting structures, be they tabs as in the implant recited in Claim 23 or anchoring fins as in the Marino implant, that extend beyond its body for, as noted, the implant will either be too large for insertion into Kuslich et al. bore 100 or, if dimensioned for insertion into bore 100, once inserted therein the implant will be incapable of achieving engaging contact between its projecting structures and chamber 102.

The implant installation method of Claim 23 is able to utilize a stepped bore (formed, e.g., as described in Kuslich et al.) because, as recited in the claim, the "at least two tabs" of the "substantially cylindrical body portion" of the implant are aligned with a space defined between adjacent vertebrae such that with rotation of the implant, the tabs will be positioned *within the enlarged diameter area of the bore*. The Kuslich et al. method does

not provide for, or contemplate, the installation of a monolithic implant such as Marino's or appellants' implant. On the contrary, Kuslich et al. is solely concerned with packing chamber 102 with a *particulate* graft medium such as *finely chopped* cortical or cancellous bone chips (specification, column 8, lines 10-13). For this, the Kuslich et al. method appears to be suitable. For accommodating Marino's or appellants' implant, the Kuslich et al. method is unsuitable. The Examiner has cited no prior art that would suggest a modification of the Kuslich et al. method that would make it suitable for installing Marino's or appellants' implant.

One skilled in the art would recognize that the Kuslich et al. spinal fusion method cannot be utilized without modification to install a Marino implant or any other kind of implant having projecting structures extending beyond its body. The examiner has made no effort to identify, in Kuslich et al., Marino or anywhere else, any suggestion or motivation for a modification of the Kuslich et al. spinal fusion method that would allow for the installation of such an implant. Lacking such a suggestion or motivation, the combination of Marino and Kuslich et al. can only be regarded as improper or as an inadequate basis for evidencing the obviousness of Claim 23. *See, In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

In addition, the Examiner fails to explain why one skilled in the art would want to use the Kuslich et al. method for installing Marino's implant when Marino's implant has *no need* for such method. The Marino installation procedure has no need for drilling and reaming operations since rotation of the implant is sufficient to cause the anchoring fins to dig into the vertebral endplates and lock the implant in place.



Therefore, it cannot be said to be obvious to apply the Kuslich et al. spinal fusion method to the installation of a Marino implant where no advantage or benefit would flow from doing so.

Respectfully submitted,

A handwritten signature in cursive script that reads "Peter G. Dilworth".

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**(9) APPENDIX**

Appealed Claims 1, 2, 4-9 and 20-24 are as follows:

1. An intervertebral implant comprising a substantially cylindrical body portion having a first end and a second end and

at least two tabs extending radially outward from the substantially cylindrical body portion, each of the at least two tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body, the body portion and tabs being formed from bone or material derived from bone.

2. An intervertebral implant according to claim 1, wherein the at least two tabs are radially spaced approximately 180° about the substantially cylindrical body portion from each other.

\* \* \*

4. An intervertebral implant according to claim 1, wherein the substantially cylindrical body portion has a longitudinal axis and at least one throughbore defined in the substantially cylindrical body portion, the throughbore having a central axis which is substantially perpendicular to the longitudinal axis of the substantially cylindrical body portion.

5. An intervertebral implant according to claim 1, wherein said substantially cylindrical body portion has a maximum diameter, and each tab of the at least two tabs has a width less than or equal to the maximum diameter of the substantially cylindrical body portion.

6. An intervertebral implant according to claim 1, wherein said substantially cylindrical body portion defines an installation slot in one end thereof.

7. An intervertebral implant according to claim 4, wherein said substantially cylindrical body portion defines an installation slot in one end thereof and a bore extending between the slot and the throughbore.

8. An intervertebral implant according to claim 4, wherein the at least two tabs are radially spaced from the throughbore.

9. An intervertebral implant according to claim 1, wherein the at least two tabs include a pair of radially opposed first tabs and a pair of radially opposed second tabs.

\* \* \*

20. The intervertebral implant according to claim 1, wherein the bone or bone-derived implant comprises animal bone.

21. The intervertebral implant according to claim 20, wherein the bone or bone-derived implant comprises human bone.

22. The intervertebral implant according to claim 1, wherein the surface of the bone or bone-derived implant is demineralized.

23. A method of installing an intervertebral implant between adjacent vertebrae comprising the steps of:

providing an intervertebral implant having a substantially cylindrical body portion and at least two tabs extending radially from the body portion;

forming a stepped bore in a portion of two adjacent vertebrae, the stepped bore having an enlarged diameter area and a reduced diameter area;

aligning the at least two tabs with a space defined between the adjacent vertebrae;

inserting the implant into the space a sufficient distance such that the at least two tabs are positioned adjacent the enlarged diameter area of the bore; and



rotating the implant to position the tabs within the enlarged diameter area of the bore.

24. An intervertebral implant comprising:

a body portion having a first end and a second end; and

at least two tabs extending radially outward from the body portion, each of the at least two tabs being longitudinally displaced from the first and second ends.